THE FAMILY NURSE PRACTITIONER ROLE IN IMPROVING HEALTH CARE FOR THE PERSON OVER 70 YEARS OF AGE WITH CHRONIC NONVALVULAR ATRIAL FIBRILLATION: THE EXPLORATION OF ANTICOAGULATION THERAPY

by

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ABSTRACT

The purpose of this project was to answer the question: Is the administration of warfarin the best practice for prevention of stroke in the person who is over the age of 70 years, who has nonvalvular atrial fibrillation (NVAF), and who is at high risk for having a stroke? A comprehensive literature review was conducted to help answer the primary research question. The findings of this review demonstrated that the administration of warfarin therapy was the best practice for the prevention of strokes in high-risk populations. The literature presented in this project further identified that although research findings support the use of warfarin therapy as best practice for prevention of strokes in the high-risk population, warfarin therapy was highly underutilized in general practice or has been managed subtherapeutically. Eight factors that may have affected the prescribing practices or suboptimal use of warfarin therapy by the health care practitioners were discussed. The project also explored how nurse practitioners can offer solutions for optimizing warfarin therapy in NVAF patients and concluded with recommendations for how nurse practitioners may help optimize treatment for patients with NVAF.

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CHAPTER 1

INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia seen in the general population. As the population ages, the incidence of AF increases dramatically. It is imperative that health care practitioners (HCPs), including family nurse practitioners (FNPs), particularly those in primary care settings, pay close attention to this condition so that early detection and prevention of complications of AF can become a priority. Within this paper, the term HCP refers to nurse practitioners (NPs) and physicians. With AF as a focus, strategies can be developed that will help the older population be as healthy as possible. The older population is the cohort that is most at risk for developing complications of AF. The focus of this paper, therefore, was on the patient who was over 70 years of age with nonvaluvular AF (NVAF). This age was selected because the majority of the studies on the treatment of NVAF have an average age of 70 to 75.

The prevalence of NVAF in the general population is between 1–12% with the prevalence increasing with the aging population. In the aging population, pharmaceutical therapies that help to reduce risks, which are associated with having NVAF, are commonly underutilized or managed suboptimally (Schumann & Ewigman, 2007). Such practices leave the aging person vulnerable to serious complications that are associated from having NVAF. The greatest risks of leaving NVAF untreated are cardiogenic shock, myocardial infraction, stroke, and death (Rao, Julka, & Paruchuri, 2009). To diminish these risks, optimal treatment of NVAF is critical (Rao et al., 2009). Therefore, treatment of NVAF is critical in order to mitigate these risks. Foremost among the risks are strokes.

This project narrowed the focus to the best methods for prevention of strokes. According to the *Canadian Stroke Strategy* (Canadian Stroke Network & Heart and Stroke Foundation of

Canada, 2010), the rate of ischemic strokes of all ages related to AF is one in six, and this increases to one in four in the octogenarian population (Rash et al., 2007). Age may play a factor in the risk for having a stroke but not all older persons are at high risk for having a stroke. The British Columbia (BC) Guidelines and Protocols Advisory Committee (2009) recommended that, prior to initiating stroke prevention therapies, HCPs complete a risk stratification tool to calculate the level of risk of a stroke for each patient with NVAF.

The research conducted for this project identified that the administration of warfarin was the best practice for prevention of strokes for high-risk patients. Warfarin is a vitamin K antagonist that works by interfering with vitamin K metabolism and helps prevent the formation of a thrombus, which is the cause of many strokes (Baker et al., 2004; Murray, 2007). The key to stroke prevention is maintaining therapeutic warfarin levels by keeping the international normalized ratio (INR) levels between 2.0 and 3.0 (Fuster et al., 2006; Gladstone et al., 2009), as this reduces the risk of thrombus formation. Despite these findings, the research further identified that warfarin therapy is significantly underutilized in the older adult population, who are at high risk of a stroke. In fact, most people over 75 years of age are either not prescribed warfarin or the warfarin therapy prescribed is at subtherapeutic levels (Gladstone et al., 2009). Management of AF with warfarin requires careful management and considerable practitioner skills and time. Factors that may contribute to subtherapeutic case management of NVAF patients' and HCPs' decision to administer warfarin and maintain therapeutic levels are examined in Chapter 2 of this project. This project reviews the role of the HCP in relation to management of the warfarin therapy and offers strategies and areas of responsibility that the FNP can assume to optimize therapeutic use of warfarin therapy in patients with NVAF. Within interdisciplinary primary care teams NPs work autonomously and in collaboration with other

HCPs. FNPs provide holistic care for patients with an emphasis on health promotion and disease prevention and have a valuable role to play in optimizing health care for patients with NVAF.

There are some patients with NVAF who are not appropriate candidates for anticoagulant therapy and alternative therapeutic choices other than warfarin therapy such as aspirin or dabigatran may be considered. It is important to note that the new drug called dabigatran, an oral-direct thrombin inhibitor, has been demonstrating promising results for preventing strokes as well and it may be more beneficial than warfarin (Connolly et al., 2009) but more studies are needed. Dabigatran has a number of positive attributes in that it has a short half-life and it does not require laboratory monitoring, which may make it the priority thrombin inhibitor of the future (Connolly et al., 2009). This new drug is beyond the scope of this paper and, until more research is conducted to verify the benefits and contraindications of Dabigatran, warfarin therapy remains the mainstay treatment for the high-risk population.

The purpose of this project is to answer the primary question: Is the administration of warfarin the best practice for prevention of stroke in the person who is over the age of 70 years, who has idea NVAF and who is at high risk for having a stroke? The question has been expanded into three subquestions:

1. If warfarin therapy is the best practice for preventing strokes in the high-risk older population, is it being managed optimally?
2. What factors contribute to suboptimal management of NVAF patient and the administration of warfarin therapy?
3. How can FNPs facilitate optimal administration of warfarin therapy?

To answer these questions, an integrative literature review was conducted and the findings are presented within the body of this project. The project begins by providing the background and context for the development of these questions.

Background and Context

Atrial Fibrillation

The Population at the Highest Risk for Developing Atrial Fibrillation

There are almost 250,000 Canadians living with AF (Heart & Stroke Foundation of BC & Yukon, 2011). The prevalence of AF increases with age and is more common in men than in women (Go et al., 2001). In the population under 60 years of age the AF rate is 1% (Fuster et al., 2006), in the population over 60 years of age the rate increases to 4% (Rosenthal et al., 2011), and in populations over the age of 75 years the rate increases further to 12% (Canadian Stroke Network & Heart and Stroke Foundation of Canada, 2010). Although AF affects the entire population, the population that is advanced in age is at a higher risk of developing AF and suffering complications of the condition such as a stroke. According to the Statistics Canada (2011) census conducted in 2006, the number of people 65 years and over was 4.3 million, which is an increase of more than 11.5% over the last 9 years. Within this cohort, 25% or 1.3 million older adults were over 80 years of age (Statistics Canada, 2009).

As the age of the population increases, more patients will potentially be at risk for developing NVAF. It is predicted that the number of patients with AF may double in future years (Gersh, Tsang, Barnes, & Seward, 2005). Therefore, screening the older population for AF needs to be considered a priority for the FNPs in primary care settings. FNPs who provide therapeutic care for patients with AF must have a broad knowledge base of AF. This section provides an in-

depth look at the definition of AF, the pathophysiology, associated risk factors, clinical manifestations, and the diagnostic process.

Definition and Classification of Atrial Fibrillation

Normal sinus rhythm, which is the normal conduction pathway in the heart, begins with a single electrical impulse from the sinoatrial node. This impulse travels in a direct path to the atrioventricular (AV) node and completes its conduction in the ventricles. AF, on the other hand, is a supraventricular arrhythmia that, if untreated, is expressed through rapid (240–320 beats/min) irregular electrical impulses that fire randomly and conduct in a disorganized and an uncoordinated pattern throughout the atria (Fuster et al., 2006). On an electrocardiogram (ECG) this uncoordinated activity is noted by the loss of P waves and the addition of rapid irregular oscillations or fibrillatory waves. The ventricular response to this random atrial activity depends on the status of the AV node and "other conducting tissues, vagal and sympathetic tone, the presence or absence of accessory pathways, and the action of drugs" (Fuster et al., 2006, p. 710). If the AV node is functional the QRS complex may be narrow (Banner, 2008; Fuster et al., 2006).

Patients with the diagnosis of AF can be grouped into two categories: (a) valvular, which includes patients with a history of valvular disease such as rheumatic mitral valve disease, prosthetic heart valves or other valvular processes, as the underlying factors contributing to their AF; and (b) nonvalvular, which includes patients with all other contributing factors for AF. Valvular AF and NVAF have different pathophysiology and require different treatment protocols. The focus of this project shifted to patients with NVAF because they represent a larger portion of patients with AF, and the majority of the major research trials have been conducted on

patients with NVAF (Manning, Singer, & Lip, 2011). Patients with NVAF are most commonly seen in an HCP's clinical practice and, therefore, represent a population that FNPs will care for.

The following presents the terms and AF classification that have been defined by the American College of Cardiology/American Heart Association/European Society of Cardiology (ACC/AHA/ESC): (a) recurrent AF is more than two episodes of AF, lasting more than 30 seconds; (b) lone AF, which occurs in patients who are less than 60 years of age and those who are without electrocardiographic evidence of cardiopulmonary disease; (c) paroxysmal AF is usually brief, lasting less than 24 hours and can last up to 7 days, and it ends spontaneously; (d) persistent AF lasts longer than 7 days and requires either electrical or pharmaceutical conversion; and (e) permanent AF, sometimes called chronic AF, lasts for at least one year and remains permanent despite attempts to convert the rhythm back to normal sinus rhythm (Banner, 2008; Fuster et al., 2006; Rao et al., 2009).

Pathophysiology and Contributing Factors

The electrical chaos that is seen in the atria of patient with AF is not absolutely understood. However, it is clear that patients with AF have structural remodelling within the heart muscle. Fibrotic patches, fatty or other infiltration, or inflammation that affect the myocardium or nodes may individually or collectively play an active role in the physiological changes that contribute to AF (Aldhoon, Melenovsky, Peichl, & Kautzner, 2010; Fuster et al., 2001). Further contributing factors may include oxidative stress injury, neurohormonal activation, and autonomic imbalance (Aldhoon et al., 2010).

Associated Risk Factors of Atrial Fibrillation

There are a number of conditions or risk factors that are associated with the development of AF (Banner, 2008; Fuster et al., 2006; Gersh et al., 2005; Go, 2005; Kellen, 2004; Rao et al.,

2009). Although not all patients with one or more of these risk factors will develop AF, there is a strong correlation between the risk factors and the development of AF. Screening patients who have risk factors commonly associated with AF may help early detection of AF and may help HCPs to initiate therapeutic interventions as early as possible, which subsequently may help to prevent negative patient outcomes such as strokes (Lip, 2009). The risk factors listed on the left-hand side of Table 1 are factors that are more commonly seen in the primary health care setting, while those listed on the right-hand side present risk factors that may be more commonly seen in specialized settings. It is important to note that some patients (10–15%) may experience AF without having any underlying risk factors (Rosenthal et al., 2011).

Table 1.
Risk Factors Strongly Associated With Atrial Fibrillation

Risk Factors Commonly Seen in Primary Health Care Setting	Risk Factors Commonly Seen in a Specialized Care Setting
Advanced age	Electrocution
Congestive heart failure	Hypertrophic cardiomyopathy
Coronary artery disease	Inflammation with elevated C-reative protein
Diabetes mellitus	Myocarditis and Pericarditis
Excessive alcohol and caffeine intake	Pulmonary embolism
Fever	Surgery (most often cardiac related)
Hypertension	
Hyperthyroidism	
Obesity	
Pneumonia	
Pulmonary diseases	
Sleep apnea	

Clinical Manifestations of Atrial Fibrillation

The most extreme clinical manifestations of AF are critical emergencies. Therefore, it is important to know the most common clinical manifestations. These include: palpitations, chest pain, dyspnea, fatigue, lightheadedness, or syncope, however, some patients are completely asymptomatic (Fuster et al., 2006). Patients who are in rapid AF can quickly become haemodynamically unstable and present with signs of "cardiogenic shock, pulmonary edema, acute myocardial infarction, or unstable angina" (Rao et al., 2009, p. 66). Rapid assessment of such critical emergencies is important so that urgent transfer of care to an acute care setting can be facilitated quickly.

Diagnosis of Atrial Fibrillation

The diagnosis of AF is often identified during a routine physical or as a result of a patient presenting with symptomatic clinical manifestation of AF. Sadly, some patients do not receive the diagnosis of AF until after they have experienced a stroke. The irregular pulse is easily detected by radial or apical exam. Definitive diagnosis comes from the interpretation of the 12-lead ECG. It is recommended that the reviewer pay special attention to wave form morphology, as AF may be confused with a number of other arrhythmias. Further, an extensive history and exam may be conducted including: medications review, tests such as a holter monitor, chest x-ray, echocardiogram, and blood profile (Banner, 2008; Rao et al., 2009). An important finding that came out of Hylek, Evans-Molina, Shea, Henault, and Regan's (2007) trial was that 19% of the $\geq$ 80 years of age group who had a previous diagnosis of chronic AF had reverted back to sustained sinus rhythm. Hylek et al.'s finding raised an important point that those patients who are diagnosed with chronic AF may not necessarily remain permanently in this rhythm, and follow-up assessments can help determine if these patients remain in AF and identify if the

patient is still a candidate for stroke prevention therapy. Once the diagnosis of AF is made, the implications of this diagnosis, such as the potential for having a stroke, must be considered and a treatment plan developed.

Stroke

One of the greatest risks for untreated AF is stroke (Rao et al., 2009). Strategies for robust AF identification, treatment, and stroke prevention may help reduce the number of people who experience a primary or secondary stroke. Patients with chronic conditions such as a strokes or AF have a significant impact on our health care system (Canadian Institute for Health Information, 2011b). It is important that all health care team members increase their awareness of methods that provide optimal care and prevention of strokes. The following section provides a definition of stroke and examines the implications of this diagnosis.

Definition and Implications of a Stroke

An ischemic stroke occurs if a stasis precipitated thrombus is formed and blocks blood flow to the brain. This type of stroke represents 80% of all stroke diagnoses (Heart & Stroke Foundation of BC & Yukon, 2011). A haemorrhagic stroke occurs when a blood vessel ruptures in the brain causing cells to die (Heart & Stroke Foundation of BC & Yukon, 2011). In NVAF patients, thrombus formation is most commonly found in the left atrial appendage and is induced by the combination of turbulent and stagnant blood flow, resulting from the uncoordinated atrial activity and platelet aggravation and hypercoagulability (Banner, 2008; Fuster et al., 2006).

In Canada, every 10 minutes someone suffers a haemorrhagic or ischemic stroke, and 15% of these strokes are attributed to AF (Heart & Stroke Foundation, 2011). Patients who do not receive treatment have a 5% chance per year of having an ischemic stroke (Albers et al., 2001; Heart & Stroke Foundation of BC & Yukon, 2011). In the Framingham Heart Study,

patients who were between the ages of 80 and 89 years and who were left untreated with AF had a 23.5% risk of having a stroke each year (Fuster et al., 2006). A person with AF who has a stroke will have more severe outcomes than an individual who has a stroke and does not have AF (Gladstone et al., 2009). Fifty percent of the people who had their first stroke related to AF will die within one year (Gladstone et al., 2009). These statistics reflect indirect cost at a community level and on the provincial health care budget. For patients with NVAF, the greatest independent risk factors for stroke are "prior thromboembolism, HF [heart failure], hypertension, increasing age, and diabetes mellitus" (Fuster et al., 2006, p. 722). The importance of early diagnosis, screening for risk factors, and excellent AF management is vital for preventing strokes and may help reduce health care expenditures in the long run.

Treatment Choice: Clinical Practice Guidelines and Risk Stratification Tools

Making the diagnosis of AF is the crucial first step in optimizing patient health care. The next most important step for preventing strokes is to initiate treatment to manage risk and prevent stroke. Deciding which treatment to initiate can be complex and complicated. However, clinical practice guidelines and risk stratification tools can help guide FNPs to make the best treatment choice.

Clinical Practice Guidelines

There are two major guidelines for HCPs in BC to follow: the British Columbia Clinical Practice Guidelines (Government of British Columbia, Ministry of Health [BC Ministry of Health], n.d.b) and the Canadian Cardiovascular Society's (2010) *Atrial Fibrillation Guidelines*. The BC guideline (Guidelines and Protocols Advisory Committee, 2009), supported by the BC Minister of Health, provides HCPs with comprehensive guidelines to care for all types of patient concerns. Within the general BC guidelines, HCPs who are caring for a person with NVAF can

access the BC's *Stroke and Transient Ischemic Attack – Management and Prevention* guideline (Guidelines and Protocols Advisory Committee, 2009) and the *Warfarin Therapy Management* guideline (Guidelines and Protocols Advisory Committee, 2010) for medical case management recommendations. The BC guidelines provide clear and concise recommendations to the HCP for administration of warfarin therapy and prevention of strokes. The focus of the BC guidelines are not specific to atrial fibrillation and do not provide comprehensive care guidelines for patients with NVAF. The Canadian Cardiovascular Society's (2010) *Atrial Fibrillation Guidelines* help to fill this gap and provide the HCP with recommendations that focus on the broader care needs of the NVAF patient. Both the BC and the Cardiovascular Society guidelines are current and evidenced based (BC Ministry of Health, n.d.b; Canadian Cardiovascular Society, 2010), and both guidelines recommend that the HCP complete the $CHADS_2$ (Cardiac failure, Hypertension, Age, Diabetes, Stroke) risk stratification assessment tool to determine the level of stroke risk and to provide recommendations for determining the appropriate antithrombus protocol.

Risk Stratification Tools

Risk stratification tools are not always straightforward, and the defining factors within the tool may not always reflect the actual patient's risk for having a stroke. In saying this, risk stratification tools provide the HCP with a foundation to begin the assessment process so that patients who are at risk of having a stroke can be identified early on the health care continuum. With early identification, risk stratification tools can highlight patients who will benefit from therapeutic treatment options such as warfarin administration. The administration of warfarin brings along with it the risk of adverse effects of the drug and, therefore, not all patients require warfarin therapy. Risk stratification tools can help balance the risk-benefit ratio of such a

therapeutic choice. Risk stratification tools further help by creating a consistent screening process for all NVAF patients, which may help to reduce the risk of a patient possibly being overlooked or considered at a lower risk for a stroke than they may actually be (Chia, 2011).

There are a number of different risk stratification tools used internationally. However, the most common tool for determining the patient's risk for having a stroke is the $CHADS_2$ tool (BC Ministry of Health, 2009a). As shown in Table 2, a single point is allocated for each criterion that the patient meets, and two points are allocated if the patient has had a prior stroke. Once the total score has been calculated the HCP considers the treatment guidelines that align with the overall score (BC Ministry of Health, 2009b).

Table 2.
Cardiac failure, Hypertension, Age, Diabetes, Stroke ($CHADS_2$) Tool

Criteria	Points
C – Recent cardiac failure	1
H – Hypertension	1
A – Age 75+	1
D – Diabetes	1
S – Prior stroke or transient ischemic attack	2

Note. From *Appendix A: Stroke risk assessment in atrial fibrillation: $CHADS_2$ score* (p. 1), by the Government of British Columbia, Ministry of Health Services, 2009, Victoria, BC, Canada: Author. Copyright 2009 the Government of British Columbia.

To prevent strokes, the $CHADS_2$ tool recommends the administration of aspirin for those patients who are at low risk for having a stroke, aspirin or warfarin therapy for individuals who are at moderate risk, and warfarin for those patients who are at high risk of having a stroke. See Table 3 for the treatment recommendations based on the $CHADS_2$ score.

Table 3.
Treatment Recommendations Based on $CHADS_2$ Score

$CHADS_2$ Score	Treatment Recommendation*
0	ASA alone
1	ASA or Warfarin (INR 2-3)
2+	Warfarin (INR 2–3)

Note. ASA = acetylsalicylic acid or aspirin; INR = international normalizing ratio. *These treatment recommendations can be made because, statistically, the probability of benefit appears to exceed the probability of harm.

From *Appendix A: Stroke risk assessment in atrial fibrillation: $CHADS_2$ score* (p. 1), by the Government of British Columbia, Ministry of Health Services, 2009, Victoria, BC, Canada: Author. Copyright 2009 the Government of British Columbia.

Patients who are assessed (by the risk stratification tool) to be in the high-risk category for having a stroke are recommended to have the HCP initiate warfarin therapy. However, the use of age as a defining risk factor for determining the therapeutic choice to initiate warfarin therapy can influence the treatment protocols. Schumann and Ewigman (2007) identified that some practitioners and guidelines use 75 years of age as a moderate risk factor, such is the case with the $CHADS_2$ (BC Ministry of Health, 2009a). Other risk stratification tools such as the American College of Chest Physicians tool use 75 years of age as a high risk factor (Singer et al., 2008).

Although the Government of BC recommends that FNPs use the BC guidelines (BC Ministry of Health, n.d.b), which direct the use of the $CHADS_2$ tool (BC Ministry of Health, 2009a), having an awareness of other existing risk stratification tools has merit. Another risk stratification tool that presents a slightly different approach to risk stratification than the $CHADS_2$ tool is found in the *ACC/AHA/ESC 2006 Guidelines for the Management of Patients with AF* (Fuster et al., 2006). This ACC/AHA/ESC tool can be found in Figure A1 in Appendix A. One other tool worth mentioning is the CHA_2DS_2VASc tool (Camm et al., 2010), which was

created by the European Society of Cardiology (ESC) and appears to provide even greater clarity for risk stratification that the $CHADS_2$ tool. The explanation for the abbreviation CHA_2DS_2VASc and tool can be found in Figure B1 in Appendix B. Awareness of different stratification tools is pertinent so that the decision to choose one tool over another is grounded in the broader knowledge that the choice of one tool over another can influence the treatment protocols.

Warfarin and the International Normalized Ratio

The $CHADS_2$ tool recommends that HCPs administer warfarin therapy for stroke prevention for patients who are at high risk of having a stroke (BC Ministry of Health, 2009a). Warfarin is a vitamin K antagonist, and it belongs to the coumarins drug class. Warfarin works by interfering with vitamin K metabolism, inhibiting synthesis of factors II, VII, IX, X, and the anticoagulant proteins C and S (Baker et al., 2004; Murray, 2007). There are a number of contraindications that indicate when warfarin should not be prescribed to patients, and these need to be considered during the assessment process prior to initiating warfarin therapy. The BC guidelines and protocols advisory committee directs HCPs to review the contraindication list and the risk factors for bleeding list; the HCP is asked to consider if the risk of bleeding outweighs the benefit of the therapy. These lists are identified in Figures C1 and C2 (see Appendix C). The key to best practice with the administration of warfarin is achieved by maintaining warfarin at therapeutic levels, which subsequently provides the patient with the best chance for the prevention of stroke.

The INR is a blood test that was established to provide standardization of the prothrombin (PT) test. The INR test helps to determine if the warfarin has reached and remains within therapeutic levels for the patient. The INR test is formulated by taking the patient's PT

and dividing it by the mean normal PT (Garcia-Alamino et al., 2010). This ratio is then calculated using the conversion factor or International Sensitivity Index, which the World Health Organization established as a standard (Garcia-Alamino et al., 2010). The literature reviewed for this project acknowledged the importance of keeping the INR level within optimal therapeutic range when treating NVAF patients with antithrombotics prophylactically. After reviewing one provincial guideline, *Warfarin Therapy Management* (Guidelines and Protocols Advisory Committee, 2010), and three national guidelines—Canadian Cardiovascular Society's (2010) *Atrial Fibrillation Guidelines*, European Society of Cardiology's *Guidelines for the Management of Atrial Fibrillation* (Camm et al., 2010), the American, *ACC/AHA/ESC Practice Guidelines* (Fuster et al., 2006)—it is clear that the INR target is 2.5 and the acceptable range for treating patients with NVAF is an INR level between 2.0 to 3.0.

Summary

In summary, this chapter identified that NVAF is commonly seen in primary care practices and if left untreated one risk of the NVAF is stroke. Stroke prevention in patients with NVAF must be the primary focus of HCPs. Clinical practice guidelines and risk stratification tools are available to help provide HCPs identify patients who are at risk of a stroke, stratify patients' level of risk, and provide recommendations for care for patients with NVAF. Following the administration of a risk stratification tool, the stratification process can identify patients who are at low, moderate, or high risk of having a stroke. For patients who are at high risk of having a stroke, the best practice for stroke prevention is the administration of warfarin therapy.

CHAPTER 2

ANALYSIS OF THE LITERATURE

This literature review was conducted to answer the main project question: Is the administration of warfarin the best practice for prevention of stroke in the person, who is over the age of 70 years, who has NVAF, and who is at high risk for having a stroke? The question has been expanded into three subquestions:

1. If warfarin therapy is the best practice for preventing strokes in the high-risk older population, is it being managed optimally?
2. What factors contribute to suboptimal management of NVAF patient and the administration of warfarin therapy?
3. How can FNPs facilitate optimal administration of warfarin therapy?

Literature Search Strategy

The main project question and subquestions 1 and 2 are discussed in this chapter and subquestion 3 is answered in the next chapter. Research reports and materials were gathered by accessing the University of Northern British Columbia's library and searching within the following search engines: Cumulated Index of Nursing and Allied Health Literature, Medline Full Text, Cochrane Database of Systematic Reviews, and Google Scholar. Databases were searched using the parameters provided in Appendix D. Reference lists of the literature cited were used to direct additional searches, and these findings were included within the overall literature review. The number of articles resulting from the search and a flowsheet identifying how the articles were then filtered and accepted for this project are provided in Appendix E.

Inclusion criteria selected for articles published by authors who lived in Canada, the United States of America, the United Kingdom, Europe, and Australia. These articles were

included as similar health care standards exist in each of these regions and provided relevance to Canadian standards. The search was limited to literature published from 2001 to 2011 to ensure that all findings were current and relevant to contemporary practice. A few older studies were included in the project as they provided foundational information, which remains relevant today. The search was also limited to literature that was written in the English language and included information relating to patients who were 70 years of age or more and who had NVAF. The Department of Justice Canada (2009) defined older persons as individuals who are over age 65 years. However, the age criterion for this project was increased to 70 years of age or older because the pertinent research used within the research findings section had inclusion criteria set at between 70 to 75 years for their study samples. As previously noted, NVAF was also a prime focus of this project. Literature that was not in English, literature that did not include patients with NVAF, literature conducted prior to 2001, and literature that focused on stroke prevention treatment that did not include warfarin therapy were excluded from the literature search.

Findings

As the rate of AF rises, HCPs require a thorough understanding of best practice for stroke prevention, which is one of the main risk factors of this diagnosis. Despite warfarin therapy being identified in research as the best practice for stroke prevention in the high-risk population, it is often not initiated or is managed subtherapeutically (Gladstone et al., 2009). This section presents research evidence that demonstrates that warfarin is the best practice and that warfarin therapy has not been managed optimally. It concludes by identifying factors that may contribute to suboptimal case management. The research findings have been grouped into three sections: research that evaluates the use of warfarin, the problem of optimal warfarin management, and the reasons for suboptimal management of anticoagulation.

Research that Evaluates the Use of Warfarin

This section of the paper presents trial findings that help to answer the study question: Is the administration of warfarin the best practice for prevention of stroke in the person who is over the age of 70 years, who has NVAF, and who is at high risk for having a stroke? Preventing strokes in the elderly population must be the principal goal of caring for patients with AF. Numerous research studies have been conducted on patients who have AF in an effort to understand best practice for prevention of thrombus and potential subsequent stroke (Dhond, Michelena, & Ezekowitz, 2003; Hart, Benavente, McBride, & Pearce, 1999; Gage, Fihn, & White, 2001; Halperin, 2005; Hart, Pearce, & Aguilar, 2007; Mant et al., 2007; Rash et al., 2007; van Walraven et al., 2002).

Meta-analysis

Two meta-analyses provide evidence to support the use of warfarin as best practice for prevention of strokes in patients with AF. Van Walraven et al.'s (2002) meta-analysis pooled data from six published trials and included a combined total of 4,052 adult patients who had been randomly assigned to oral anticoagulant or aspirin with or without anticoagulant and were followed for 1.9 years. Although the criteria included all ages of adults, the mean age was 71.7 years old. Persons with permanent AF accounted for 67% of the entire population, and 65% of the population in this analysis had a high risk for having a stroke (van Walraven et al., 2002). The findings from van Walraven et al.'s analysis concluded that the risk of stroke was significantly lower in the oral anticoagulant group compared to the aspirin group (2.4 vs. 4.5 events per 100 patient-years). The absolute risk reduction in the low-risk group was 0.4%, while in the high-risk group it was 3.3% (van Walraven et al., 2002). These results support the use of warfarin therapy as the best treatment for prevention of strokes in the high-risk population but

highlight the importance of risk stratification. The participants who were taking warfarin in this meta-analysis had almost double the chance of experiencing a major bleed than those who received aspirin (2.2 vs. 1.3 events per 100 patient years). This is concerning, however, in analyzing van Walraven et al.'s findings, although nine patients would experience a bleed over a period of a year, this risk is outweighed by the fact that if the HCP prescribed warfarin to 1,000 patients during the same time frame the HCP would be able to prevent 23 ischemic strokes.

One limitation to van Walraven et al.'s (2002) research was that it included a large number (1,215) of patients from the SPAF III trial, who were taking a combination of low-dose warfarin with aspirin at the same time. Combination therapy could have affected the findings, however, van Walraven et al. resolved this conflict by removing patients who had been on the combination therapy and conducted the study a second time. The trial was rerun including the remaining 2,837 patients; interestingly, the results barely changed (2.4 in those taking warfarin vs. 3.8 in those taking aspirin) and warfarin remained the superior choice for prevention of strokes. Although the overall findings support the use of warfarin, the relative benefit of warfarin therapy compared to aspirin for prevention of strokes was higher in the under 75 year old population compared to the over 75 year old population (p for interaction = .08). However, the risk of bleeding did not change between the two age groups (van Walraven et al., 2002).

The second meta-analysis conducted by Hart et al. (2007) compared aspirin and warfarin for pharmaceutical treatment in prevention of a stroke in patients. This analysis included the six trials that were part of the van Walraven et al. (2002) meta-analysis. The strength of this analysis was that it was a much larger study, including 29 randomized trials with a combined total of 28,044 patients with NVAF. The analysis included studies that were conducted between 1966 and 2007. The results were significant and showed that warfarin reduced strokes by 60% while

antiplatelets reduced the risk strokes by 20% (Hart et al., 2007). The results of this meta-analysis further demonstrated that warfarin produced a 25% reduction in the death rate when compared with patients who had no antithrombotic treatment (Hart et al., 2007). In support of warfarin as the best practice for prevention of strokes, this meta-analysis demonstrated that the risk of haemorrhage was less than the absolute reduction in strokes. Although Hart et al.'s meta-analysis identified that the rate of intracranial haemorrhage doubled with the use of warfarin (when compared to aspirin), the absolute risk increase was low at 0.2%. This meta-analysis added to the literature that supported the use of warfarin in prevention of strokes (van Walraven et al., 2002). One limitation to consider in regards to risk of bleeding was that most of the population within Hart et al.'s meta-analysis was already taking warfarin prior to participating in the studies. The first 90-days transition period, which puts the patient at the highest risk for a having a bleed (Hylek et al., 2007), was avoided. Consequently, these findings might be higher if the population was different.

A second limitation to this project is that Hart et al.'s (2007) study included patients of any age, but the average age was 70 years old. Hart et al. acknowledged that age was the greatest risk for bleeding. This study focused on the younger older adult, and Hart et al. acknowledged that they were not confident that their study findings would be identical for the octogenarian population. Additionally, the patients included in Hart et al.'s meta-analysis were generally healthy, independent, and 62% of the study patients were male. Although this statistic is representative of the fact that more men than women develop AF (Rosenthal et al., 2011), Hart et al.'s results may not fairly represent the same outcomes for the female population. As the BC population ages, it is important to consider the ramification of age when calculating the bleeding risk and it may also be important to question if male and female patients have the same response

to warfarin therapy. Further, Hart et al.'s study sample may not be reflective of the more complex and less independent patients the HCPs might see in their practice today.

The limitations to both van Walraven et al.'s (2002) and Hart et al.'s (2007) meta-analyses included trials that had target INRs that varied between 2.0 and 4.2. Four of the six trials included in van Walraven et al.'s analysis, which were also included in the Hart et al.'s analysis, had INRs over the optimal 2.0–3.0, which could have contributed to some of the bleeds found in van Walraven et al.'s study. Both meta-analyses included a mix of trials that were conducted in both the primary care settings and acute care settings (Hart et al., 2007; van Walraven et al., 2002). Warfarin initiated and managed in the acute care settings may not be reflective of general practice, as environmental factors and strict INR controls are in place. It is important to consider trials that reflect the primary care setting, as this is more reflective of the majority of the settings that older adults will receive warfarin therapy. Mant et al. (2007) supported this idea, and their trial and Rash et al.'s (2007) trial presented findings that focused on primary care settings.

Single Trials

One single trial that was not included within Hart et al.'s (2007) and van Walraven et al.'s (2002) meta-analyses provided further evidence to support the meta-analyses conclusion that warfarin was best practice for preventing strokes in the elderly with AF. The Birmingham atrial fibrillation treatment of the aged study (BAFTA) was conducted in England and Wales between 2001 and 2004 (Mant et al., 2007). The 973 eligible patients included in the BAFTA trial were all 75 years of age and older (Mant et al., 2007). Patients were randomly assigned to either take aspirin (75 mg/day) or dose-adjusted warfarin (Mant et al., 2007). The INR was kept between 2.0–3.0 with the target INR at 2.5 (Mant et al., 2007).

The strength of Mant et al.'s (2007) trial is that it provided evidence based on a primary care setting rather than a hospital or controlled environment. The primary care provider assessed patients every 6 months, and INR testing was conducted as per the primary care provider's usual practice (Mant et al., 2007). There were 24 primary events (21 strokes and 2 intracranial haemorrhages) in the warfarin group and 48 primary events in the group taking aspirin (Mant et al., 2007). The BAFTA trial demonstrated that warfarin was safer and more effective than aspirin in preventing strokes (Mant et al., 2007). Mant et al. reported that patients assigned to the warfarin arm of the trial had a lower yearly risk of intracranial (1.8%) and extracranial (1.4%) haemorrhage than those taking aspirin (3.8% and 1.6% respectively). The overall yearly risk of a major bleed in BAFTA was 2% (Mant et al., 2007). Mant et al.'s trial demonstrated that age was not a contraindication for taking warfarin. For all age groups warfarin had the same risk of major haemorrhage, death, hospitalizations related to a nonstroke vascular event, or increase the mortality when compared to those patients taking aspirin. Among patients over 85 years of age who were on warfarin there was a 27% less chance of a major haemorrhage (Mant et al., 2007), which was interesting because few trials, including Hart et al.'s (2007) and van Walraven et al.'s (2002) meta-analyses, have been able to isolate the very old population and assure the HCP that the haemorrhage risk was low. More trials that target research on this population are needed to provide the HCP with increased confidence that their patients are at a low risk of experiencing a bleed when on warfarin therapy.

Rash et al. (2007) conducted a trial testing the efficacy and safety of warfarin against aspirin for stroke prevention in octogenarians with AF (WASPO). Although the WASPO trial was included within Hart et al.'s (2007) meta-analysis and although it was not large enough to generalize to all octogenarians, the strength of Rash et al.'s trial was that it helped to fill the gap

in predicting outcomes in the octogenarian population and it provided evidence based on primary care settings. In 2006, the WASPO trial, conducted in the United Kingdom, included persons who were between 80 and 90 years of age (Rash et al., 2007). In Rash et al.'s trial, 36 patients were randomized to receive dose-adjusted warfarin (INR between 2.0–3.0) and 39 patients received aspirin 300 mg/day. All patients were ambulatory and had permanent AF (Rash et al., 2007). Patients were followed for one year, with assessments completed every 3 months in primary care settings.

One limitation was that Rash et al.'s study was a small trial, with only 75 patients. However, this trial was able to significantly demonstrate that adjusted-dose warfarin was far superior to aspirin, having fewer adverse side effects (6% vs. 33% respectively) in the over 80-year-old population. Rash et al.'s study also excluded patients who had previously been on warfarin. Therefore, the risk of bleeding results would not have reflected the first 90 days of warfarin therapy, which is the highest risk period for bleeds (Hylek et al., 2007). Another limitation to Rash et al.'s study was that it prohibited participation of any elder who had fallen once within 12 months of the study. Although this exclusion criterion reflects safety concerns for the patient's risk of potentially falling and having a bleed, it may have resulted in a study population that was not reflective of the general population. I was unable to find studies that predicted the outcome for a patient who fell one or two times in a year, continued to be at high risk of a stroke, and chose to accept the risk of warfarin therapy. It raises the question, how many falls (if any) are too many to benefit from receiving warfarin therapy? Future research might consider exploration of this question.

A third single trial, the stroke prevention in atrial fibrillation (SPAF II) trial, also included within both Hart et al.'s (2007) and van Walraven et al.'s (2002) meta-analyses,

supported the use of warfarin as best practice for stroke prevention. The SPAF II trial was conducted in the United States over a period of 2.3 years and demonstrated that the benefit of dose-adjusted warfarin was the most effective treatment for preventing strokes in patients with AF (Halperin, 2005; "Warfarin Versus Aspirin," 1994). The SPAF II trial compared the effectiveness of warfarin and aspirin in two groups of patients: 715 patients who were under the age of 75 years of age and 385 patients who were over 75 years of age (Halperin, 2005; "Warfarin Versus Aspirin," 1994). After 3 years, the SPAF II trial found warfarin to be mildly more effective than aspirin (Halperin, 2005). The primary event rate in the group of participants over 75 years of age was 3.6% with warfarin and 4.8% with aspirin. However, the over 75 years of age cohort who received warfarin had a 1.8% per year risk of intracranial haemorrhage (Halperin, 2005). Although the SPAF II study demonstrated that the benefit of warfarin therapy outweighed the aspirin therapy for prevention of strokes, it concluded that the risk for bleeding in the older population needs to be carefully considered in the decision-making process for initiating warfarin ("Warfarin Versus Aspirin," 1994).

The fourth single trial that supported warfarin therapy as best practice for prevention of strokes in the high risk population was the SPAF III trial, which enrolled 1,044 patients with AF, including 523 high-risk participants (Gage et al., 2001). Gage et al.'s (2001) SPAF III trial evaluated if combining 325 mg aspirin with a low fixed-dose warfarin (INR target 1.2–1.5) would demonstrate beneficial outcomes compared to dose-adjusted warfarin (INR target 2.0–3.0). The trial was stopped after 1.1 years when significantly higher rates of ischemic stroke and systemic embolization (7.9% vs. 1.9%) occurred in the combined group (Dhond et al., 2003). SPAF III concluded that combination therapy showed no therapeutic benefit and dose-adjusted

warfarin therapy was more effective for the patient without causing increased haemorrhagic complications (Dhond et al., 2003; Halperin, 2005; Hart et al., 2007).

In summary, two meta-analyses and four single studies were reviewed to answer the study question. The conclusion drawn from these studies was that the administration of warfarin was the best practice for prevention of stroke in the person who is over the age of 70 years, who has NVAF, and who was at high risk for having a stroke (Dhond et al., 2003; Halperin, 2005; Hart et al., 2007; Mant et al., 2007; Rash et al., 2007; van Walraven et al., 2002; "Warfarin Versus Aspirin," 1994). Stroke prevention in patients with NVAF is paramount, and the optimal management of warfarin therapy must be in the forefront of FNPs minds.

The Problem of Optimal Warfarin Management

This section answers the study subquestion: If warfarin therapy is the best practice for preventing strokes in the high-risk older population, is it being managed optimally? Despite guidelines and research recommendations consistently identifying the importance and efficacy of warfarin management in older persons who are at high risk of a stroke, numerous research results identify that the majority of patients are not prescribed anticoagulation therapy by the HCP or that anticoagulation therapy has been initiated but remains subtherapeutic (Dhond et al., 2003; Gattelari, Worthington, & Zwar, 2008; Gladstone et al., 2009; Tulner et al., 2010). Consequently, despite the literature stating that warfarin is the best drug therapy for many patients (Dhond et al., 2003; Halperin, 2005; Hart et al., 2007; Mant et al., 2007; Rash et al., 2007; van Walraven et al., 2002; "Warfarin Versus Aspirin," 1994), there seems to be a gap between best practice recommendations and HCPs' practice. The following section will present research findings that highlight the fact that the majority of patients are not adequately anticoagulated. The focus of this section will be on the role of the HCP in suboptimal warfarin use and not on the patient's

role. The goal of this section is to identify suboptimal areas of practice so that strategies for FNPs to improve therapeutic use of warfarin therapy could be identified.

Research findings that identify reduced warfarin administration rates are not new. Over 10 years ago Go et al. (1999) conducted the "Warfarin Use Among Ambulatory Patients with Nonvalvular Atrial Fibrillation: AnTicoagulation and Risk Factors in Arial Fibrillation (ATRIA)" study. The ATRIA study was conducted between 1996 and 1997 and included 11,082 people of all ages with NVAF in a large medical outpatient clinic setting (Go et al., 1999). In Go et al.'s study evidence of AF was confirmed via ECG 80% of the time. Interestingly, confirmation of AF with ECG technology was not completed in some of the other studies reviewed for this project. Of the participants who had no known contraindications and who could have been candidates for warfarin therapy, only 55% were prescribed warfarin and for participants 85 years of age or older the percentage dropped to 35.4% (Go et al., 1999). A few years later, Burton, Hamilton, Isles, and Norrie's (2001) study found similar low prescribing rates of warfarin. Burton et al.'s study involved 30 primary care practices and included 858 patients with NVAF who were considered appropriate candidates for warfarin. Within Burton et al.'s (2001) study the researchers found only 36.2% of the 858 patients were prescribed warfarin. Schumann and Ewigman (2007) added to these findings by evaluating the administrative practice of warfarin; they also focused on the person who was over 75 years of age person with NVAF. Similarly, Schumann and Ewigman's research found that only 50% of eligible participants were prescribed anticoagulants.

Ten years later, research continues to demonstrate that warfarin therapy remains underutilized despite research demonstrating it is best practice. Gladstone et al. (2009) studied 597 patients who experienced a primary stroke and 323 patients who experienced a secondary

stroke prior to admission to one of 12 stroke centres in Ontario between 2003 and 2007. All study participants were over the age of 75 years and were known to have NVAF. After reviewing hospital records, Gladstone et al. reported their concern that older persons with NVAF appeared to be managed subtherapeutically in the community. Of the patients who were eligible for warfarin therapy on admission, Gladstone et al. found 40% of patients were prescribed warfarin, 30% were prescribed aspirin, and 29% had no antithrombotic. Most importantly, 75% of those taking warfarin had subtherapeutic INR levels on admission, and only 10% of the overall population in the study with known AF were therapeutically anticoagulated (Gladstone et al., 2009).

There were three main limitations to Gladstone et al.'s (2009) study. First, the researchers did not have access to the patient history regarding reasons why patients may not have been prescribed warfarin. Second, the AF diagnoses were confirmed by a review of each patient's medical history records and were not confirmed by ECG. Third, the American College of Chest Physicians risk stratification tool was used (Singer et al., 2008), which automatically places patients in the high risk category if they are over 75 years of age. This is different from the $CHADS_2$ tool (BC Ministry of Health, 2009a), which BC HCPs use today. In Gladstone et al.'s study, HCPs using the American College of Chest Physicians risk stratification tool (Singer et al., 2008) may not have classified some of the patients as being high risk or requiring warfarin therapy, which would lower the patient's eligibility criteria for this study. All studies I reviewed concluded patients who were at high risk of having a stroke were not being optimally prescribed warfarin therapy or had been managed subtherapeutically (Burton et al., 2001; Dhond et al., 2003; Gattelari et al., 2008; Gladstone et al., 2009; Go et al., 1999; Schumann & Ewigman, 2007; Tulner et al., 2010), which increases the risk to these older persons for having a stroke.

Reasons for Suboptimal Management of Anticoagulation

This section answers the subquestion: What factors contribute to suboptimal management of NVAF patient and the administration of warfarin therapy? NVAF patients may not receive warfarin therapy for reasons such as allergies or the patient having other contraindications. However, there are cases in which HCPs overlooked a potential candidate for therapy. Research identifies that warfarin is best for prevention of strokes in high-risk persons, so why do we continue to see a significant number of patients not started on warfarin therapy or managed subtherapeutically? Is this an intentional omission of warfarin therapy, or is there further critical information obtained by the HCP that is not recognized in the current guidelines or risk stratification tools? Perhaps the current stratification tools do not reflect the detailed assessment process that goes into the HCP's decision regarding warfarin prescribing. This section explores factors that affect the HCP practice in maintaining the warfarin therapy at optimal levels or that deter the HCP from initiating therapy. The factors discussed include fear of the patient bleeding, fear of the patient falling, underestimating the patient's stroke risk, fear of patient noncompliance, fear of the patient developing cognitive decline, patient and HCP beliefs, the HCP's prescribing practices, and the time needed to manage patient care.

Fear of Bleeding

The first and most common reason that the HCP may not initiate warfarin therapy or may initiate suboptimal levels of warfarin therapy is the HCP's fear that the patient will have a potential complication from a bleed. Researchers have clearly indicated that warfarin therapy is the best practice for prevention of strokes in the high-risk patient (Hart et al., 2007; Mant et al., 2007; van Walraven et al., 2002). These researchers supported warfarin therapy despite the risk that the patient may haemorrhage because they found that the risk was lower for bleeding than

the risk of the patient experiencing a stroke. Hylek et al.'s (2007) research added to the discussion about risk of bleeding but presented a very different perspective to the findings presented in the "Research that Evaluates Warfarin Therapy" section of Chapter 2. Hylek et al.'s study focused on the risk of bleeding in persons who were over the age of 80 years with NVAF, and their research questioned if this cohort had been fairly represented in previously published research studies. Hylek et al.'s study included 472 patients who were started on warfarin between 2001 and 2003 and were followed for one year. Of the 472 patients, 32% were greater than or equal to 80 years of age and 91% had at least one stroke risk factor (Hylek et al., 2007). Of the participants who were 80 years of age or older, the incidence of major haemorrhage was 13.1%, while those under 80 years of age had an incidence of 4.7% (Hylek et al., 2007). It is concerning that the risk of bleeding in the 80 years of age or older cohort was over 2.5 times the rate of those patients under 80 (Hylek et al., 2007). Hylek et al.'s study adds validity to some HCPs' fear that their patients may experience a bleed while taking warfarin. These HCPs may initiate alternative therapy to warfarin for treatment of their patients who have NVAF. As valid as these fears maybe in some cases, HCPs should not allow these fear to overshadow the decision-making process, including the risk analysis, as many patients are still appropriate candidates for use of warfarin therapy.

Fear of Falls

The second reason an HCP may not initiate warfarin therapy is the HCP's fear that the patient will fall and suffer a subsequent bleed. As patients age, their balance and gait patterns may alter. Appreciating that older patients are at a higher risk for falls, Schumann and Ewigman (2007) acknowledged that a history of falls or a patient who is at risk of falls is a contraindication for anticoagulation therapy. Nevertheless, Tulner et al. (2010) drew a strong conclusion against

this fear. Tulner et al. identified that in one year a patient would have to fall 295 times to be considered a contraindication for warfarin administration. They further concluded that subdural haematomas and intracranial haemorrhages from a fall are uncommon and should not influence the HCP from prescribing warfarin therapy to eligible patients.

According to the BC Warfarin Therapy guidelines (Guidelines and Protocols Advisory Committee, 2010), falls are not identified on either "the absolute contraindication" list nor on the "some relative contraindication" list, which are highlighted in tables in the main part of the BC guideline. Table 2 (included in Figure C2 in Appendix C) in the guidelines document does, however, identify falls as a risk factor for bleeding complications from warfarin therapy (Guidelines and Protocols Advisory Committee, 2010, p. 4). This guideline leaves the decision to administer warfarin up to the HCP (Guidelines and Protocols Advisory Committee, 2010), but recommends the HCP weigh the risks of bleeding against the benefit of the therapy. The HCP's interpretation of distinction between contraindications, risk factors, and his or her perception about how many falls classifies "falls" as a risk factor or contraindication that would prohibit warfarin therapy may affect the HCP's clinical judgment on whether or not warfarin therapy should be administered.

Underestimating the Patient's Stroke Risk

The third reason the HCP might not initiate warfarin therapy is because he or she may have underestimated the patient's risk for stroke. It is crucial to identify the best candidates to receive warfarin. Therefore, the decision to administer warfarin, with a known risk factor for a major bleed, does require thorough risk stratification. Doucet et al.'s (2008) prospective trial was conducted in four geriatric hospital settings. Doucet et al. followed 209 older inpatients (84.7 +/- 7 years of age) with chronic AF for 3 months and examined the decision-making parameters that

the HCP used to determine whether the patient would receive aspirin or warfarin therapy. Doucet et al. found that in one third of all the patients thromboembolic risk was underestimated and physicians overestimated the risk of bleeding in half of all the patients. Using the $CHADS_2$ test (BC Ministry of Health, 2009a) on high-risk patients, Doucet et al. calculated the theoretical risk of a thromboembolic event at 98% and the theoretical haemorrhagic risk at 17%, while physicians subjectively calculated the risk for these same patients to have a thromboembolic event at 65% and haemorrhagic risk at 38%. For 3 months following discharge from the hospital, each patient's prescription for warfarin or aspirin was left unchanged and the Doucet et al. found that there was no increase in patient outcomes including bleeding, death, or ischemic events. The limitation of this trial was that Doucet et al. included patients with prior valvuloplasties, which was not part of the inclusion criteria for this project. However, the findings are significant in terms of the decision-making process and outcomes. Additionally, current risk stratification tools may be too simplified to reflect the complexities of the patient profile. Despite risk stratification tools recommending the administration of warfarin, the HCP may chose to follow or not to follow this recommendation due to their in-depth holistic assessment.

Fear of Patient Noncompliance

The fourth reason the HCP may not initiate warfarin therapy is the fear the person will not take the drug as ordered, obtain routine INR testing, or maintain necessary lifestyle choices that do not interfere with the warfarin therapy. A subtrial within the WASPO trial assessed patients with NVAF for medication compliance by using a Medication Event Monitoring System, which Rash et al. (2007) described as,

> [An] electrical system that is designed to compile the dosing histories of ambulatory patients prescribed oral medications. The system comprises two parts: a standard plastic

> vial with threaded opening and a top for the vial that contains a micro-electric circuit that registers when the vial is opened and when it is closed. (p. 152)

The medical compliance aspect of Rash et al.'s trial lasted four weeks and demonstrated that older persons were 96.4% compliant, with correct dosing. Rash et al.'s trial affirmed that older adults in their study were able to manage complex anticoagulant therapy independently.

Although Rash et al.'s (2007) findings demonstrated that the older persons in their study had no problem maintaining compliance for the warfarin therapy regime, Waterman et al. (2004) presented another side to the question of whether the older person can strictly adhere to the medication regime. Waterman et al. found 23% of patients were out of range in their INR levels and patients who were 80 years of age or older had the most out-of-range INR results. The overall findings in Waterman et al.'s study showed that 36% of the time INRs were out of range (lower than 1.8 and higher than 3.4) it was due to the patients' noncompliance in following the medication regime. In Waterman et al.'s study, noncompliance was due to consumption of vitamin K through dietary intake, alcohol consumption, misunderstanding around instructions about the dose to take, failure to fill or refill the prescription, or refusal to take the medication.

Fear of the Patient Developing Cognitive Decline

The fifth reason HCPs may not prescribe warfarin therapy or that warfarin therapy may be subtherapeutic is that older patients may have or be at risk of developing cognitive decline or has a cognitive deficit. In these cases, the HCP's lack of confidence in the patient's ability to manage his or her own therapy safely, combined with the HCP's inability to routinely monitor the patient, are realistic drawbacks for primary care providers. The Public Health Agency of Canada (2010) identified that 400,000 older persons were living with dementia and predicted that this number would double in 30 years. Patients taking warfarin and other medications need to be

competent to ensure safety of medication administration. Since cognitive decline and dementia is a progressive disease, it may not easily be recognized in the early stages. The commitment to completing ongoing competency assessments and fear that the patient may not be able to follow the warfarin therapy protocols may give HCPs pause for initiating the therapy in the first place (van Deelen, van den Bemt, Egberts, van't Hoff, & Maas, 2005).

Patient and Health Care Practitioner Beliefs

The sixth reason the HCP may not initiate warfarin therapy is that the patient and HCP may have a different values or beliefs on taking warfarin. Values related to the risk of bleeding, the risk of having a stroke, adherence to pharmaceutical regime, clinical guidelines, drug interactions, and the time and cost of monitoring the therapy can all play into the HCP's decision to initiate treatment or the patient's decision to accept or decline the therapy (Garcia-Alamino et al., 2010). Hylek et al.'s (2007) trial demonstrated that the patient's belief around the benefit or safety of a drug could significantly alter therapeutic use of warfarin therapy. In Hylek et al.'s study 26% of the cohort who were 80 years of age or older discontinued taking warfarin within the first year after the study ended, and 81% of patients who had stopped taking warfarin were due to the patient's and/or the HCP's perceptions around safety concerns, bleeding, falls, nonadherence with drug monitoring, coagulopathy, and dermatologic concerns. In van Walraven et al.'s (2002) meta-analysis the opposite belief system was revealed; older persons in this study felt they would rather take warfarin therapy, comply to the medication regime, and risk having a bleed than not take the medication and risking having a stroke. Identifying patient and HCP beliefs around anticoagulation therapy can take time, as can highlighting areas of difference and desires to the approach to care. Some patients simply may not want warfarin therapy, and the HCP would have no choice but to accept the patient's wishes and provide an alternate approach

to prevention, despite the HCP's good intention to provide the more therapeutic option of warfarin therapy.

The Health Care Practitioner's Prescribing Practices

The seventh factor that affects the prescribing practices of warfarin is the HCP's specialty and/or location of practice. Kellen (2004) and Halperin (2005) both identified that internists and cardiologists prescribed anticoagulation therapy at a much higher rate than family or general practitioners. Kellen furthered this differentiation by identifying that HCPs practicing in rural environments are less likely to anticoagulate their patient than urban HCPs. Perhaps this is due to factors that inhibit optimum use of the drugs, such as a lack of local facilities for INR testing or hospitals in the event that urgent care is needed.

The Time Needed to Manage Patient Care

The final reason that warfarin therapy may not be prescribed or managed subtherapeutically is the amount of time required to manage the medication protocols. The responsibilities and time for managing patients with NVAF can be extensive. Many HCPs simply do not have the time and resources to provide in-depth AF care on their own. Dhond et al. (2003) highlighted that many physicians find anticoagulation management time consuming and inconvenient. In fact, Cohen et al.'s study (as cited in Dhond et al., 2003) stated that 94% of physicians surveyed in the United Kingdom preferred that another care provider handle anticoagulation management. Time or lack thereof may be creating gaps in health care.

Bajorek, Ogle, Duguid, Shenfield, and Krass's (2007) study examined how warfarin use could be improved. Bajorek et al. conducted group discussions and one-on-one interviews with 49 key players in the healthcare system in Australia, including nurses, pharmacists, and general practitioners, along with 14 patients with AF who were over the age of 65. The first key finding

from Bajorek et al.'s study was that both the HCP and the patient with AF found that it was difficult to obtain current, detailed information on AF and warfarin therapy. Patients in Bajorek et al.'s study identified that although they wanted detailed explanations, patients also wanted the information conveyed to them at a slower pace than they were provided by their HCP, so that they could absorb the information (Bajorek et al., 2007). Sadly, the patients in Bajorek et al.'s study felt abandoned by the HCP in their anticoagulation therapy and felt that they were responsible for their own learning.

Summary

In summary, this chapter presented findings of a literature review that evaluated warfarin therapy. The studies concluded that the administration of warfarin therapy was the best practice for the prevention of strokes in the high-risk older patient with NVAF. Despite warfarin therapy being identified as best practice, research was presented that identified that warfarin is highly underutilized or is managed subtherapeutically in the older population. Eight factors, including fear of the patient bleeding, fear of the patient falling, underestimating the patient's stroke risk, fear of patient noncompliance, fear of the patient developing cognitive decline, patient and HCP beliefs, HCP's prescribing practices, and the time needed to manage patient care, were discussed. The next chapter will consider these eight factors and will provide a discussion that addresses the role that FNPs could play to help optimize administration of warfarin therapy in primary care settings.

CHAPTER 3

IMPLICATIONS FOR NURSE PRACTITIONERS' PRACTICE

This chapter considers the project's third subquestion: How can FNPs facilitate optimum care of the older person with NVAF and therapeutic administration of warfarin therapy? The administration of warfarin has been underutilized in many health care practices, and new approaches are needed to provide NVAF patients with a more consistent management of their condition. FNPs are members of interdisciplinary teams of HCPs. By utilizing more NPs in the health care system, NVAF patients' access to health care could be increased.

According to Pulcini, Jelic, Gul, and Loke (2010), NPs "represent a sleeping giant for healthcare systems worldwide" (p. 37), and I believe that BC would benefit by tapping into this resource. By increasing FNPs in primary health care, older patients may have increased access to care and may receive a more consistent approach to their health care and for their warfarin therapy. FNPs work autonomously and collaboratively with other HCPs in providing comprehensive primary care to persons with NVAF. Currently, there are over 1,990 NPs in Canada (Canadian Institute for Health Information, 2011a), of which 186 are in BC (College of Registered Nurses of British Columbia [CRNBC], 2011). In BC, FNPs care for patients "with common acute and chronic physical and mental diseases, disorders and conditions" (CRNBC, 2009, p. 6). The FNPs scope of practice includes diagnosing patients, ordering and interpreting diagnostic tests, and prescribing medications (Canadian Nurses Association, as cited in Canadian Nurses Association, 2008). This chapter provides an expanded discussion outlining specific responsibilities that FNPs can assume to help optimize warfarin therapy. FNPs responsibilities discussed include providing increased access to general screening, completing physical health assessments and referrals, completing risk stratification tools, medication requirements and

screening for warfarin interactions, and completing mental health assessments. The chapter also discusses methods for increasing FNPs confidence in warfarin therapy, which includes reducing the FNP's fear of the patient having a bleed while on warfarin therapy, reducing the FNP's fear of the patient falling, and improving warfarin therapy compliance in the patient. Finally, this chapter ends by supporting the role of FNPs as an interdisciplinary, collaborative team member.

How Family Nurse Practitioners Can Optimize Warfarin Therapy

General Screening Process

The first way that FNPs can reduce suboptimal warfarin therapy is for FNPs to provide screening services to increase the number of older patients who are screened for AF. The decision to initiate warfarin therapy or not requires the HCP to have confidence in knowing the patient. The comprehensive patient data collection begins far before the prescription for warfarin therapy is ever written. In most cases, the initial data collection begins during the initial screening process that the HCP provides to all his or her patients.

FNPs are trained to approach their patients holistically and to emphasize health promotion and disease prevention (CRNBC, 2009), so the current NP scope of practice supports the FNPs in initiating relevant screening processes. The screening process may be used within the FNP's office setting or FNPs may consider setting up a portable screening clinic that could offer increased access to screen a greater number of older persons within the community. Screening for AF need not be separate from the FNP's existing screening processes; FNPs typically utilize a general screening process to look for risk factors for common chronic conditions, which include risk factors for AF and stroke.

If FNPs were to consistently approach prevention of risk factors, they could provide multiple patients benefits (BC Ministry of Health, 2008). Although people are living longer in

the 21st century, Gersh et al. (2005) stated we are a "'sicker population' having a higher prevalence of comorbid conditions including hypertension, diabetes, CHF [congestive heart failure]" (p. C7), and obesity. Importantly, these four comorbid conditions are not only risk factors for stroke but they are also risk factors for AF (Gersh et al., 2005). By increasing overall screening within the older population, early identification of AF may be achieved, which may support earlier implementation of therapies, thereby reducing the potential risks of leaving AF untreated.

Completing Health Assessments and Referrals

The second way that FNPs could help reduce suboptimal warfarin therapy involves FNPs providing comprehensive assessments to patients and identifying the appropriate candidates for warfarin therapy. FNPs have advanced training in patient health assessments and can complete and document detailed systematic assessments. If FNPs diagnoses a new arrhythmia while conducting an assessment, FNPs have the authority to complete specialist physician referrals for the patient (CRNBC, 2011). By facilitating a referral to the cardiologist, FNPs create access for the patient to specialized care. FNPs are also authorized to order (a) all laboratory tests as set out in the Medical Services Commission Payment Schedule (conditions apply, see document); (b) any diagnostic services listed in MSC Laboratory Medicine Payment Schedule or on the CRNBC's *Scope of Practice for Nurse Practitioners* list; and (c) any imaging services, as long as it is on the list outlined within the CRNBC's (2011) *Scope of Practice for Nurse Practitioners: Standards, Limits and Conditions* document. To improve the efficiency of the patient's first meeting with the consulting specialist, FNPs would be able to order diagnostic tests such as an ECG, a holter monitor, or laboratory screening in advance of the specialist meeting. The FNPs would also be able to interpret the results of the tests for patients, which may help reduce

potential anxiety for seeing a specialist. They could also provide clarification to the patient after the specialist visit if needed. FNPs would also be able to assess patients for any manifestations of AF and determine if the patients are stable or if they need to be transferred to an acute care facility. The comprehensive approach to care that FNPs offer provides comfort and reassurance to concerned patients (Thrasher & Purc-Stephenson, 2008).

Risk Stratification

FNPs are able to integrate their assessment data and assist in increasing utilization of warfarin therapy, by completing a risk stratification tool to determine the patient's level of risk for having a stroke. It is recommended that patients who meet the criteria to be anticoagulated based on a risk stratification tool such as the $CHADS_2$ test be prescribed warfarin (BC Ministry of Health, 2009a). If the patient cannot tolerate warfarin due to side effects, allergies, or patient–FNPs choice, the FNPs would then be available to provide alternative stroke prevention strategies such as aspirin therapy. To reduce the risk of underestimating the patient's thromboembolic risk, as was the case in Doucet et al. (2008) study, FNPs can ensure that the risk stratification tool is consistently utilized for every NVAF patient. FNPs can maintain a practice that is current and up to date, utilizing new guidelines and new risk stratification tools as they become available, which may offer more comprehensive screening process. Deplanque et al.'s (2004) study recognized that HCPs lacked up-to-date knowledge of pathophysiology and of current literature on trials and guidelines. FNPs who are motivated to stay current and up to date may consider networking with each other to ensure they are continuing to provide evidence-based care.

Medication Requirements and Screening for Warfarin Interactions

FNPs could provide pharmaceutical requirements for patients with NVAF and cross-check for interactions with other medications or products that reduce the efficiency of warfarin therapy. It is within FNPs' scope of practice to write prescriptions for their patients. Drugs that the FNPs can prescribe are listed within the CRNBC (2009) *Scope of Practice for Nurse Practitioners* document in three categories: (a) "No Exceptions" drugs, which means the FNPs can prescribe the drug with no exceptions; (b) "C" category drugs, which means FNPs can prescribed the drug with continuation only restrictions; and (c) "O" category drugs, which means FNPs cannot prescribe the drug. Warfarin is a drug that falls under the AHFS 20:00 category Blood Formers and Coagulators and is considered a no-exception drug (CRNBC, 2011; S. Wade, personal communication, October 20, 2011). Therefore, FNPs can meet NVAF patients' pharmaceutical requirements for warfarin therapy.

It is important to recognize that FNPs have the legal authority to write prescriptions for their patients, review previously ordered medications, and make alterations if needed because many patients over the age of 70 have multiple pharmaceutical requirements. The Canadian Institute for Health Information (2011b) confirmed this need, reporting that three in four older persons have at least one chronic condition. NVAF and strokes fall under the umbrella of chronic disease care and those with three or more chronic conditions are taking six or more medications (Canadian Institute for Health Information, 2011b). Canadian Institute for Health Information (2011b) further identifies that older person with chronic conditions do not have their medications reviewed frequently enough, and FNPs are in a good position to be able to conduct medication reviews. The Public Health Agency of Canada (2010b) added a further concern and identified

that "50% of prescriptions are not taken properly" (p. 30) and "up to 20% of hospitalizations of people over the age of 50 are the result of problems with medications" (p. 31).

Although all HCPs are working under time restrictions, FNPs have a reputation for spending more time with their patients in general (Horrocks, Anderson, & Salisbury, 2002), taking the time to review patient medications, and explaining the side effects of medications. By listening to questions, and sharing information with patients, FNPs provide patients with tools to promote better self-directed care (McCauley, Bixby, & Naylor, 2006) and improve patient confidence in understanding their prescribed medications. Patient education and therapeutic communication techniques may help to reduce hospitalizations and improve patient compliance to medication regimes.

FNPs can manage warfarin therapy safely by conducting regular reviews of the patients' medications to ensure there are no drugs interactions with the warfarin therapy. Medications can also be included in the discussion between the FNPs and their patients. Over the counter drugs such as acetaminophen and aspirin are often not considered medications by the older persons as they do not require a prescription and, therefore, may be seen as unimportant (Gage et al., 2001). Hylek et al. (2007) supported the need to review over-the-counter medications with patients, as they found 40% of the overall trial population combined aspirin with their warfarin therapy. The practice of combining warfarin with aspirin significantly increased the patient's risk of complications. Of the 26 haemorrhages seen in Hylek et al.'s study, 46% (12) were from the group that had combined aspirin and warfarin therapy. Medication interactions can have a significant negative impact on the patients. Therefore, it is important for FNPs to cross-check all medications.

FNPs can help prevent suboptimal warfarin therapy. This can be achieved by: (a) reviewing the *Important Interactions with Warfarin* patient resource (BC Ministry of Health, n.d.a) with the patient; (b) sharing information on naturopathic remedies such as herbal products (see Appendix F), which can significantly alter the level of warfarin; and (c) reviewing the *Warfarin and Food: Guide for Patients* (BC Ministry of Health, n.d.e), which identifies foods that containing vitamin K and can alter the therapeutic effect of warfarin. By providing the information at a slow pace and providing a written copy of the resources reviewed for the patient to take home, FNPs may increase the older person's understanding and retention of the information.

Alcohol and smoking cigarettes are other products that can reduce the therapeutic benefit of warfarin therapy and put the patient at risk for complications (BC Ministry of Health, n.d.a). Small to moderate amounts of alcohol may not have a significant affect. However, heavy drinking and binge drinking can have serious consequences. Patients who drink heavily are at risk of: (a) falling more frequently, (b) eating poorly balanced diets, (c) forgetting to take their medications or taking the wrong dosage, (d) developing gastritis, (e) bleeding, and (f) forgetting to following through with INR testing (Baker et al., 2004). FNPs' strong communication and counselling skills (Charlton, Dearing, Berry, & Johnson, 2008; Conlon, 2010) may help support effective management of these patients and their warfarin therapy. FNPs may also be able to help facilitate a referral to an alcoholic detoxification program, smoking cessation program, or other support program if the patient desires.

Completing Mental Competency Assessments

FNPs can help reduce suboptimal warfarin therapy by providing mental competency assessments to evaluate their patient's ability for self-administration of medications. Assessment

of the patient's mental competency takes time, cannot be rushed, and requires ongoing commitment to evaluating the patient's status (Kellen, 2004). FNPs, with a nonjudgmental, trusting, and respectful manner, may present a discussion around mental health issues so that patients will feel comfortable discussing their life experience. Mental competency assessments are important when working with the elderly population because, as the patient ages, the mental health that once provided a stable foundation for coping with life can become overwhelmed by the changes resulting from the disease and aging process (BC Ministry of Health, 2008).

By completing regular mental competency assessments FNPs may be able to improve the older patient's outcomes. Stress, anxiety, depression, and cognitive changes can all contribute to suboptimal warfarin therapy. To ensure that the patient is competent and is an appropriate candidate for warfarin therapy, the FNPs are able to conduct the Mini-Mental State Examination (BC Ministry of Health, n.d.c), the Montreal Cognitive Assessment tool (Nasreddine, 2011), and depression screening on a regular basis. Van Deelen et al. (2005) researched older persons with AF and cognitive impairment and showed that a mini–mental state examination score of less than 23 was associated with suboptimal INR levels. FNPs have the skills to provide support to the older patients whose mental health may be changing. FNPs approach care with the awareness that health is interconnected with all aspects of the patient (McCauley et al., 2006). FNPs possess a strong ability to create trusting relationships through good communication skills (McCauley et al., 2006), which may allow FNPs to discern a change in the patient's mental status earlier than other HCPs. Shifts in cognition may cause the patient to no longer be competent or safely managing their warfarin therapy. The FNP's ability to assess cognitive functioning is essential for ensuring the patient can manage their own medication regime including warfarin therapy.

Communication

Nurses have extensive training in communicating with a variety of patients, and the FNP's scope of practice only adds to this skill set. Having good listening skills, not rushing patients, and providing enough time to answer all of the patients' questions helps FNPs to develop a therapeutic relationship with their patients (Charlton et al., 2008). FNPs can foster and empower patients and their families to become a partner in their own health care (BC Ministry of Health, 2008). It is important that FNPs be cognizant of all the factors that affect the decision-making process for prescribing warfarin or withholding the drug treatment and question the validity of their decisions. In addition, open conversations that provide the patient the opportunity to express his or her wishes is important. Allocating enough time for sharing information with the patient so that his or her decision-making process comes from a well-informed position is critical. An important observation in Bajorek et al.'s (2007) European study was that HCPs had a misconception that their colleagues were providing decision-making information to the patients, when in actuality the communication system was flawed, leading to patients receiving incomplete information. The assumption that another HCP was educating the patient is likely generalizable to other countries, including Canada. FNPs can ensure that they take on the responsibility for providing information to their own patients, which will reduce the chance that their patients do not fully understand the implications of warfarin therapy.

Increasing Family Nurse Practitioners' Confidence in Warfarin Therapy

Reducing the Fear of Bleeding

Reducing the FNP's fear that the patient may experience a bleed may help to reduce suboptimal warfarin therapy. Strategies that focus on the reduction of bleeding risk factors such as the ongoing management of anticoagulation therapy, patient education, and prevention

activities (e.g., dietary monitoring) that have been previously discussed are crucial and can help FNPs have greater confidence in reducing the patient's likeliness of experiencing a bleed. As FNPs find a greater sense of confidence, they may find they increase the opportunity for more patients to receive warfarin therapy. Since the primary focus in NVAF patient care is to prevent a stroke, FNPs with strong communication skills can encourage and support the patient in being diligent with their warfarin administration and ensure regular INR testing practices. The most important role in primary prevention of strokes is try to ensure patients stay within the INR target range. Keeping the INR between 2 and 3 will also reduce the risk of a bleed that higher INR results can bring.

Hylek et al.'s (2007) findings raised the concern for risk of bleeding in the elderly population; this research may be considered when the HCP is considering initiating warfarin therapy and determining the frequency of INR monitoring. Hylek et al. identified that 58% of major bleeds within their study occurred within the first 90 days of initiation of warfarin. Therefore, it is vitally important that the FNPs keep a vigilant watch on INR levels and watch for any signs of bleeding during this critical period. The fear that a patient might be at risk for a significant bleed related to the administration of warfarin is always at the forefront of the FNP's mind. Without the rigours of monitoring the INR and keeping the INR level within the therapeutic range there will be a reduced benefit to initiating warfarin therapy.

Portable prothrombin testing units may provide FNPs with a method to help patients maintain their INRs within therapeutic range. Portable prothrombin testing units or point-of-care (POC) devices provide increased access to INR levels. Garcia-Alamino et al.'s (2010) meta-analysis looked at the effects of self-monitoring and self-management as compared to standard therapy. This study included 4,723 patients from 18 trials and revealed that American patients

who conducted self-monitoring and self-management had a 50% reduction in thromboembolic events, 13% reduction in major haemorrhages, and a 36% reduction in all-cause mortality (Garcia-Alamino et al., 2010). Further, Garcia-Alamino et al.'s study found that self-monitoring reduced major haemorrhages significantly with little risk to the patient. Having instant INR result would allow FNPs to make immediate adjustments to the warfarin therapy either in the FNP's office or in the patient's home. Access for HCP to incorporate POC devices into their practice may foster more holistic patient care.

FNPs are uniquely situated to provide such monitoring and evaluative services for NVAF patients. Any INR results that are not within the target zone will prompt the FNPs to follow up with patients to reassess possible contributing factors and determine if warfarin therapy should be continued. When FNPs initially starts the patient on warfarin therapy they may wish to allocate extended time for providing information to the patient. The goal is for their patients to understand all the implications of warfarin therapy and make informed decisions. FNPs can encourage the patient to be involved in understanding the INR values and diligent scheduling of the INR testing by using the *Warfarin Therapy Management* guidelines record (Guidelines and Protocols Advisory Committee, 2010). On this form, the patient can record their INR levels and any instructions for the warfarin dosing. To reduce the potential risk of anxiety related to the discovery of bleeding, FNPs can provide the patient with information about signs of bleeding. FNPs can further review the BC guideline *Warfarin; A Guide for Patients* (BC Ministry of Health, n.d.d), which identifies signs that could trigger the patient to contact the primary HCP.

Reducing the Fear of Falls

It is important for FNPs to consider if the fear of the patient falling is a personal bias or if it is clinically reasonable. When considering personal bias, FNPs can look to Tulner et al.'s

(2010) study, which drew a strong conclusion against the fear that the patient will experience a bleed as a result of a fall while on warfarin therapy. Tulner et al. suggested that in one year a patient would have to fall 295 times for falling to be considered a contraindication for warfarin administration. Further, Tulner et al. identified that subdural haematomas and intracranial haemorrhages from a fall are uncommon and should not influence the practitioner from prescribing warfarin therapy to eligible patients. Reducing risk factors for falls around patients is important, and can help reduce the FNPs' fear of the patient falling. FNPs can gain further reassurance by completing detailed fall assessment tools, which might help provide FNPs with a more in-depth understanding of the individual patient's risk for falls. With detailed assessment data FNPs can make a more confident decision to administer or withhold warfarin therapy.

Strategies to Reduce Noncompliance

Increasing the patient's compliancy rate with medication regimes will reduce suboptimal warfarin therapy. FNPs may allocate additional time in their practice to provide their patients with information, counselling, and ongoing support for the management of warfarin therapy. By providing patients with comprehensive information, patients' compliance to therapy may improve. Older persons with NVAF require information around the diagnosis, the treatment options, and the risks if the diagnosis goes untreated. FNPs are highly trained and carry the knowledge to provide patients with information they will require to manage their own health. The amount of time that is required to meet the patient's initial and ongoing information needs can be significant. The Public Health Agency of Canada (2010) identified a few reasons why extended time is needed for the educational process in the older adult population:

> Only one in eight adults (12%) over age 65 has adequate health literacy skills for many basic health-related decisions. Age is associated with lower health literacy of seniors due

> to several factors, . . . slower processing of new information, higher incidence of mild cognitive impairment and dementia, and increased vision and hearing impairment. (p. 40)

To meet patients' needs, the FNPs could consider offering information sessions for patients, patients' families, and the general public. This can be achieved through one-on-one sessions or by providing group inservices. One method FNPs can take under consideration is providing thorough and time-efficient health care for patients in a group medical visit. Group visits can offer a broader reach to multiple patients and can be incorporated into a 1- to 2-hour timeframe (McLaren, 2008). Patients benefit because they get to hear other patient's questions, concerns, and experiences, allowing for a greater grasp of knowledge. Most importantly, by making time in a group setting to share information and answer questions, FNPs may be able to avoid having patients feel "abandoned" (Bajorek et al., 2007, Discussion section, para. 3) and "alone" (Delegation of Responsibility for Warfarin Therapy section, para. 4) in their health care experience.

Family Nurse Practitioners as a Health Care Resource

The final responsibility that FNPs can take on for reducing suboptimal warfarin therapy is to become an active member of an interdisciplinary collaborative health care team. Health care is changing, and new strategies need to be considered to meet the growing demand of the aging population, their complex needs, and the chronic diseases and conditions, including NVAF, that often effect members of this cohort. A solution to the growing health care gap is the increased utilization of FNPs to help fill the primary health care needs of the older population. FNPs offer not only the autonomous ability to function as independent primary care provider but they are also guided by their *Scope of Practice* (CRNBC, 2009) to maintain collaborative interdisciplinary relationships, which supports FNPs to endorse team member relationships.

When professional resources are unavailable, it may be important for society to reconsider how professional resources are utilized.

Research studies support the use of FNPs for reducing time constraints and for meeting patient health care needs. Ducharme, Alder, Pelletier, Murray, and Tepper (2009) found that when FNPs were involved in patient care in emergency rooms, the benchmark wait time was reduced by 2.1 times and the length of stay was reduced by 48.8%. The findings from McCauley et al.'s (2006) study identified that FNPs improved patient outcomes, adherence to medications and treatment plans, patient's quality of life, and reduced hospitalization and overall health care costs. Finally, Thrasher and Purc-Stephenson's (2008) study concluded that patients were highly satisfied with the FNP's care. These three studies are among many that have highlighted the significant role that the FNPs can play by having a more prominent role in providing primary health care for patients.

Health Canada (2011) suggested that professional roles should be clarified and the scope of practice within each professional body should be utilized to its greatest capacity. By implementing a collaborative team-based model, professionals, including FNPs, can be more efficient in use of professional assets. By working with a collaborative approach, Health Canada (2007) stated, Canadians will have "better health outcomes, improved access to services, improved use of resources, and greater satisfaction for both patients and providers" (Preface section, para. 4) if professional teams are supported. By collaborating in teams, FNPs can maximize all the skills they have within their *Scope of Practice* (CRNBC, 2009) to optimize patient with NVAF and their health care needs, including warfarin therapy. By encouraging FNPs to take on the entire patient care needs or by providing support through a shared-care

approach with another HCP, patients who are at risk for complications from their NVAF may be managed optimally.

Summary

This chapter addressed the research subquestion: How can FNPs facilitate optimum care of the older person with NVAF and therapeutic administration of warfarin therapy? I described how FNPs can optimize warfarin therapy, discussed approaches for increasing FNPs' confidence in warfarin therapy, and last, I discussed the FNPs' role within an interdisciplinary collaborative health care team. The next chapter is the final chapter in this report and details the findings from the extensive literature review.

CHAPTER 4

RECOMMENDATIONS AND CONCLUSION

The purpose of this project was to answer the primary question: Is the administration of warfarin the best practice for prevention of stroke in the person who is over the age of 70 years, who has NVAF, and who is at high risk for having a stroke? Findings from an extensive literature review were used to answer the project questions and expand the discussion throughout the project. Evidence presented within this project suggests that many patients who meet the criteria to have warfarin therapy initiated by the HCP have either not been prescribed warfarin or warfarin therapy has been managed suboptimally (Dhond et al., 2003; Gattelari et al., 2008; Gladstone et al., 2009; Tulner et al., 2010). The research studies reviewed for this project evaluated administrative practices of warfarin therapy, initiated by the HCP. Studies found that between 35.4% and 55% of the eligible participants over 75 years of age, were prescribed warfarin (Go et al., 1999; see also Burton et al., 2001; Schumann & Ewigman, 2007). Gladstone et al.'s (2009) study identified that 75% of the patients who were taking warfarin were subtherapeutic. The studies reviewed for this project, highlighted that a significant number of patients had suboptimal warfarin therapy; these patients remained at risk of having a strokes.

A number of factors were identified within the project that contributed to HCPs' suboptimal management of warfarin therapy. These factors included underestimating the patient risk for having a stroke and requiring warfarin therapy, having risk stratification tools that do not reflect the patient profile, having a fear that the patient will bleed or have a fall and develop a subsequent bleed, and finally being fearful of the patient being noncompliant to medication regimes. The HCP's job specialty, the HCP's beliefs (along with the patient's beliefs) about warfarin therapy, and a lack of time were identified as contributing factors that may affect

patients from either receiving optimal warfarin therapy or from receiving optimal management of the warfarin therapy by the HCP.

FNPs bring a unique body of knowledge and skill that can provide for the comprehensive care for patients with AF. As such, FNPs can help facilitate optimal administration of warfarin. FNPs can help reduce suboptimal use of warfarin therapy by providing increased access to screening for NVAF, completing physical and cognitive assessments, completing risk stratification tools, completing referrals to specialist, and meeting patient requirements for pharmaceutical needs and laboratory tests and patient requirements for education. There are methods for reducing FNPs' fear of bleeding remains a concern in many FNPs' practice. To help alleviate some of these fears, FNPs can: (a) regularly monitor INRs to ensure that they are in therapeutic range, (b) increase supervision of the patient and INRs during the first 90 days, (c) complete regular assessments for interactions with all substances, and (d) educate the patient. By working within their full scope of practice FNPs may reduce strokes by improving therapeutic management of warfarin for the older persons with NVAF.

Numerous research studies have been conducted on patients who have NVAF in an effort to understand best practice for prevention of thrombus and potential subsequent strokes. The research reviewed for this project suggests that the administration of warfarin therapy by the HCP is the best practice for the prevention of strokes in the high-risk person with NVAF who is over the age of 70 years. Warfarin significantly reduced strokes better than antiplatelets and remains best practice. HCPs should not avoid the initiation of warfarin therapy in their patients for fear of their patient bleeding as the studies examined found although the risk of a bleed is a real potential, the benefits of stroke prevention outweigh the low risk of a patient experiencing a bleed.

The older population is growing, and with this expansion comes the potential increase in persons who will experience NVAF. These future patients will require health care for their AF and possibly management of warfarin therapy. The implications of a patient having a stroke are vast and multifaceted. Stroke prevention strategies such as the administration of warfarin in the high-risk populations are important to consider. However, it is important to provide evidenced-based care, and gaps still exist in the available research to date. Research and clinical trials that have been reviewed for this project have mainly focused on the 70- to 80-year-old cohort. The research has not been able to provide solid evidence that therapeutic practices for the older population (i.e., those over 80 years of age) will have the same outcome as those who are younger. It would be important to see further research conducted in primary care settings to see if warfarin continues to be the best choice for prevention of strokes in high-risk populations or if the risk of haemorrhage is higher in settings that are less controlled than hospital-based clinical trials. Research is continually exploring new practices and drug therapies for the management of patients with NVAF. It is pertinent that the HCP stays current in evolving best practice therapies.

Recommendations

With the research finding that this project has identified in mind, this project proposes three recommendations for improving the therapeutic management of patients with NVAF, who are high risk of stroke and require warfarin therapy: a recommendation for FNPs and the patient, for FNPs and the interdisciplinary team, and for FNPs and the Ministry of Health.

The first recommendation relates to FNPs and the patient. FNPs can increase patient knowledge acquisition (individually and at the community level) and increase support around patient needs related to AF and warfarin therapy. This could be achieved by providing accessible

office hours, phone services, counseling services, web-based services and/or group medical visits.

The second recommendation relates to FNPs and the interdisciplinary team. FNPs can foster increased peer and interdisciplinary knowledge of NVAF and warfarin therapy, including creating methods to share current clinical practice guidelines and the results of current research studies. FNPs can also collaborative with health care teams to develop strategies that focus on reducing the number of strokes in patients with NVAF.

The third and last recommendation relates to FNPs and the Ministry of Health. FNPs can advocate to the Ministry for an increase in the numbers of FNPs who work with patients with NVAF. FNPS can advocate to support work environments and jobs that are conducive to therapeutic management of NVAF, which may optimize therapeutic management of warfarin. This may be achieved by FNPs advocating for the opening of AF clinics or creating funding to create new roles for FNPs to become NVAF consultants. FNPs can advocate to increase methods and technology for monitoring INR levels more therapeutically, such as supporting the use of Point-of-Care devices.

Conclusion

The most common arrhythmia seen in the general population is AF, and the incidence of AF continues to rise. Primary health care includes health promotion, illness prevention, holistic health assessment, diagnosis, and treatment, which are all services FNPs are uniquely qualified to provide (Canadian Nurses Association, 2005; Health Canada, 2006). To meet the growing demands of NVAF patients, FNPs will have to overcome obstacles, but one that I must recognize is that FNPs in BC are a small cohort. There is much FNPs can offer for making improvements to the services that the health care system currently offers older persons with NVAF. With only

186 NPs in BC (CRNBC, 2011), it will be important that all NPs work together to support a collective advancement in the profession.

FNPs are well situated to help reduce the risk of strokes in the 70 year old and older population with NVAF by optimizing warfarin therapy. I believe that if FNPs are supported in their full scope of practice for providing care to patients with NVAF, that complications related to NVAF could be reduced. If Health Canada and other health professionals support FNPs, patients with NVAF could receive the benefits that this health care team member could provide. It is time for Canada to embrace the role of FNPs and reap the health care benefits this professional body has to offer.

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APPENDIX A: ACC/AHA/ESC RISK STRATIFICATION TOOL

Risk Category	Recommended Therapy
No risk factors	Aspirin, 81 to 325 mg daily
One moderate-risk factor	Aspirin, 81 to 325 mg daily, or warfarin (INR 2.0 to 3.0, target 2.5)
Any high-risk factor or more than 1 moderate-risk factor	Warfarin (INR 2.0 to 3.0, target 2.5)*

Less Validated or Weaker Risk Factors	Moderate-Risk Factors	High-Risk Factors
Female gender	Age greater than or equal to 75 y	Previous stroke, TIA or embolism
Age 65 to 74 y	Hypertension	Mitral stenosis
Coronary artery disease	Heart failure	Prosthetic heart valve*
Thyrotoxicosis	LV ejection fraction 35% or less	
	Diabetes mellitus	

*If mechanical valve, target international normalized ratio (INR) greater than 2.5.
INR indicates international normalized ratio; LV, left ventricular; and TIA, transient ischemic attack.

Figure A1. Antithrombotic therapy for patients with atrial fibrillation.

Note. From "ACC/AHA/ESC practice guidelines: ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation – Executive Summary," by V. Fuster, L. E. Ryden, D. S. Cannom, H. J. Crijins, A. B. Curtis, K. A. Ellenbogen, . . . S. Wann, 2006, *Circulation, 114*, p. 723, Table 10.

APPENDIX B: THE $CHA_2DS_2VAS_C$ RISK STRATIFICATION EXPLANATION AND TOOL

The explanation for the abbreviation CHA_2DS_2VASc that follows is taken from the ESC's "Guidelines for the Management of Atrial Fibrillation" (Camm et al., 2010):

> This risk factor-based approach for patients with non-valvular AF can also be expressed as an acronym, CHA_2DS_2VASc [congestive heart failure, hypertension, age $\geq$ 75 (doubled), diabetes, stroke (doubled), vascular disease, age 65–74, and sex category (female)]. This scheme is based on a point system in which 2 points are assigned for a history of stroke or TIA, or age $\geq$ 75; and 1 point each is assigned for age 65–74 years, a history of hypertension, diabetes, recent cardiac failure, vascular disease (myocardial infarction, complex aortic plaque, and PAD, including prior revascularization, amputation due to PAD, or angiographic evidence of PAD, etc.), and female sex (Table 8). (p. 2382)

(a) Risk factors for stroke and thrombo-embolism in non-valvular AF	
'Major' risk factors	**'Clinically relevant non-major' risk factors**
Previous stroke, TIA, or systemic embolism Age ≥75 years	Heart failure or moderate to severe LV systolic dysfunction (e.g. LV EF ≤40%) Hypertension - Diabetes mellitus Female sex - Age 65–74 years Vascular disease[a]

(b) Risk factor-based approach expressed as a point based scoring system, with the acronym CHA_2DS_2-VASc (Note: maximum score is 9 since age may contribute 0, 1, or 2 points)	
Risk factor	**Score**
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age ≥75	2
Diabetes mellitus	1
Stroke/TIA/thrombo-embolism	2
Vascular disease[a]	1
Age 65–74	1
Sex category (i.e. female sex)	1
Maximum score	**9**

(c) Adjusted stroke rate according to CHA_2DS_2-VASc score		
CHA_2DS_2-VASc score	**Patients (n=7329)**	**Adjusted stroke rate (%/year)[b]**
0	1	0%
1	422	1.3%
2	1230	2.2%
3	1730	3.2%
4	1718	4.0%
5	1159	6.7%
6	679	9.8%
7	294	9.6%
8	82	6.7%
9	14	15.2%

Figure B1. CHA2DS2VASc risk stratification tool.

Note. From "Guidelines for the Management of Atrial Fibrillation," by Camm et al., 2010, *European Heart Journal, 31,* p. 2382, Table 8.

APPENDIX C: CONTRAINDICATIONS FOR WARFARIN

Absolute Contraindications	Some Relative Contraindications
• The presence of a severe or active bleeding diathesis • Non-adherence to medication and INR monitoring • Pregnancy[2] (avoided at least during the first trimester and from about 2 to 4 weeks before delivery) • Allergy or intolerance to warfarin (consider warfarin alternative - Nicoumalone)	• Uncontrolled hypertension (greater than 180/100 mm Hg) • Severe liver disease • Recent surgery and procedures involving the nervous system, spine or eye

Figure C1. Contraindications for warfarin.

Note. From *Warfarin Therapy Management* (p. 1), by the Guidelines and Protocols Advisory Committee, 2010, Victoria, BC, Canada: Queen's Printer. Copyright 2010 by the Guidelines and Protocols Advisory Committee.

Table 2: Risk Factors for Bleeding Complications of Anticoagulation Therapy[1,9,18]	
Risk Factor Category	**Specific Risk Factors**
Age	> 70 years
Time Period	Within first year of warfarin treatment
Cardiac	Uncontrolled hypertension, heart failure
Gastrointestinal	History of gastrointestinal haemorrhage, active peptic ulcer, hepatic insufficiency
Hematologic/Oncologic	Thrombocytopenia, platelet dysfunction, coagulation defect, underlying malignancy
Neurologic	History of stroke, cognitive or psychological impairment
Renal	Renal insufficiency
rauma	Recent trauma, history of falls
Alcohol	Excessive alcohol intake
Medications	Use of aspirin or other NSAIDs; Discontinuing medications that reduce INR; See Medication Interaction Table

Adapted from: Warfarin Reversal Position Statement, Australasian Society of Thrombosis & Hematosis[19]

Figure C2. Risk factors for bleeding complications of anticoagulation therapy.

Note. From *Warfarin Therapy Management* (p. 4), by the Guidelines and Protocols Advisory Committee, 2010, Victoria, BC, Canada: Queen's Printer. Copyright 2010 by the Guidelines and Protocols Advisory Committee.

APPENDIX D: LITERATURE REVIEW SEARCH PARAMETERS USED TO CONDUCT LITERATURE REVIEW

Parameter Description	Parameter Specifications
Time frame	From 2001 through to 2011
Indications	Atrial fibrillation, nonvalvular atrial fibrillation, arrhythmia and atria; cerebrovascular disease, and stroke.
Medication terms	warfarin, aspirin; platelet aggregation inhibitors; platelet aggregation; and anticoagulant.
Limiters	Full text, peer reviewed
Key words	Nurse practitioner, nurse; aged, aged 80 and over, age 70 years and over; frail elders, senior; elder abuse; multidisciplinary care team, multidisciplinary, collaborative care, collaboration, holistic; medications, pharmaceutical (s); medication compliance, medication regimen, self-medication; physiopathology; guidelines, practice guidelines, clinical practice guidelines; INR; education; adult education; prevention; evidence based, best practice; nursing practice, and evidence.

APPENDIX E: SEARCH ENGINE RESULTS – NUMBER OF HITS PER WORD

Table E1.
Keywords Searches Per Database

	Database		
Key Words	CINHAL	MEDLINE	COCHRANE
nurse practitioner	654	752	288
nurse	23940	18794	5571
atrial fibrillation (AF)	918	4011	3477
arrhythmia	591	3691	3522
arrhythmia, atrial	12	-	-
anticoagulant	163	2220	2107
warfarin	574	2071	2044
platelet aggretion inhibitors or platelet aggregation inhibitors	404	0	0
stroke	5101	17287	18860
aspirin	1161	3912	7730
international normalized ratio or INR	206	995	696
aged	37952	337875	250225
aged 80 & over	37952	69849	2262
over 70	-	558	2296
frail elder	1269	7	0
senior	1293	3028	1141
elder abuse	877	-	-
multidisciplinary	4561	0	1812
multidisciplinary care team	3445	0	-

	Database		
Key Words	CINHAL	MEDLINE	COCHRANE
collaborative or collaboration	6016	5345	4701
holistic	1669	2717	309
medications	2354	10784	25976
pharmaceutical	3040	0	-
pharmaceuticals	214	0	1481
medication compliance	1429	809	343
medication regimen	39	121	144
physiopathology	13720	105959	2450
self-medication	130	538	232
guidelines	11135	30556	11472
practice guidelines	6729	841	-
clinical practice guidelines	253	841	649
education	65573	81639	22602
adult education	138	55	47
prevention	53040	124505	40268
evidence based	9713	16633	46
best practice	986	1192	342
nursing practice	7724	2155	248
evidence	21186	129869	53221

Note. Search date: July 2011.

Figure E1. Flow Chart of Search Strategy

Literature Search Strategy

Primary Source	Non-Academic Source	Reference Page Source
Cumulated Index of Nursing Allied Health Literature Medline Full Text Cochrane Database of Systematic Reviews	Google Scholar Google Internet Search	Reference lists of the literature cited were used to direct additional searches, and these findings were included within the overall literature review .

Initial Search : Total 192 Resources
These resources were divided into 5 Categories

90 Single studies	**13 Meta-analysis/ Systematic Review/Cochrane Review**	**10 Guidelines:**	**53 Discussion Papers**	**26 Internet Resources:**
35 NP Practice 51 AF/ Stroke/and Anticoagulation Therapy (i.e., Warfarin/ Dabigatran/ Clopidogrel/ Aspirin) 4 Other: Theories on Aging, Geriatric Assessment, Falls, Homebound Seniors	6 Meta-analysis/ Systematic Review 7 Cochrane Review	1 Provincial 9 National Guidelines	13 NP/ Nursing 40 AF	3 Heart/Stoke 13 Ministry: 4 NP 3 Collaboration 6 Population Statistics on age and health 4 Pathophysiology 7 Nursing Association

78 Resources were utilized in this project.
These resources were divided into 4 Categories

43 Atrial Fibrillation Pathophysiology Anticoagulation Therapy:Warfarin Stroke	**10 Guidelines and Practice Protocols**	**15NP Practice**	**10 Government Statistics and Charters**

APPENDIX F: HERBAL PRODUCTS THAT SIGNIFICANTLY ALTER THE LEVEL OF WARFARIN

Herbal Products	
Ferverfew	Dnashen
Ginger	Dong qua
Ginkgo	Fenugreek
Horse chestnut	Garlic
Pau d'arco	Saw palmetto
Vitamin e	Alfalfa
Green tea	Ginseng
Ubiquinone (coenzyme Q10)	St. John's wort